

Food and Drug Administration, HHS

§ 352.3

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PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE [STAYED INDEFINITELY]

Subpart A—General Provisions

Sec.

352.1 Scope.

352.3 Definitions.

Subpart B—Active Ingredients

352.10 Sunscreen active ingredients.

352.20 Permitted combinations of active ingredients.

Subpart C—Labeling

352.50 Principal display panel of all sunscreen drug products.

352.52 Labeling of sunscreen drug products.

352.60 Labeling of permitted combinations of active ingredients.

Subpart D—Testing Procedures

352.70 Standard sunscreen.

352.71 Light source (solar simulator).

352.72 General testing procedures.

352.73 Determination of SPF value.

352.76 Determination if a product is water resistant or very water resistant.

352.77 Test modifications.

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EFFECTIVE DATE NOTE: At 64 FR 27687, May 21, 1999, part 352 was added, effective May 21, 2001. At 65 FR 36319, June 8, 2000, the effective date was delayed until Dec. 31, 2002. At 66 FR 67485, Dec. 31, 2001, the effective date was stayed until further notice.

EFFECTIVE DATE NOTE: At 68 FR 33380, June 4, 2003, the stay on part 352 was lifted and amendments were made to §§352.20, 352.52, and 352.60, effective June 4, 2004. At 68 FR 33381, June 4, 2003, part 352 was again stayed until further notice, effective June 4, 2004.

Subpart A—General Provisions

§ 352.1 Scope.

(a) An over-the-counter sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not

misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 352.3 Definitions.

As used in this part:

(a) *Minimal erythema dose (MED)*. The quantity of erythema-effective energy (expressed as Joules per square meter) required to produce the first perceptible, redness reaction with clearly defined borders.

(b) *Product category designation (PCD)*. A labeling designation for sunscreen drug products to aid in selecting the type of product best suited to an individual's complexion (pigmentation) and desired response to ultraviolet (UV) radiation.

(1) *Minimal sun protection product*. A sunscreen product that provides a sun protection factor (SPF) value of 2 to under 12.

(2) *Moderate sun protection product*. A sunscreen product that provides an SPF value of 12 to under 30.

(3) *High sun protection product*. A sunscreen product that provides an SPF value of 30 or above.

(c) *Sunscreen active ingredient*. An active ingredient listed in § 352.10 that absorbs, reflects, or scatters radiation in the UV range at wavelengths from 290 to 400 nanometers.

(d) *Sun protection factor (SPF) value*. The UV energy required to produce an MED on protected skin divided by the UV energy required to produce an MED on unprotected skin, which may also be defined by the following ratio: $SPF \text{ value} = MED(\text{protected skin (PS)}) / MED(\text{unprotected skin (US)})$, where MED (PS) is the minimal erythema dose for protected skin after application of 2 milligrams per square centimeter of the final formulation of the sunscreen product, and MED (US) is the minimal erythema dose for unprotected skin, i.e., skin to which no sunscreen product has been applied. In effect, the SPF value is the reciprocal of the effective transmission of the product viewed as a UV radiation filter.